IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF WEST VIRGINIA
AT CLARKSBURG

ASTRAZENECA AB and ASTRAZENECA PHARMACEUTICALS LP, *Plaintiffs*, v. MYLAN PHARMACEUTICALS INC. and KINDEVA DRUG DELIVERY L.P., *Defendant*.	Civil Action No. 18-cv-193-IMK-RWT
ASTRAZENECA AB and ASTRAZENECA PHARMACEUTICALS LP, *Plaintiffs*, v. MYLAN PHARMACEUTICALS INC. and KINDEVA DRUG DELIVERY L.P., *Defendants*.	Civil Action No. 18-cv-203-IMK-RWT

JOINT STIPULATIONS OF FACT

For the purpose of this case only, the parties stipulate to the following facts which require no proof at trial:

I. THE PARTIES

1. Plaintiff AstraZeneca AB is a corporation organized and existing under the laws of Sweden, with its principal place of business at S-151 85 Södertälje, Sweden.

2. AstraZeneca AB is the current assignee and owner of U.S. Patent No. 10,166,247 ("the '247 patent").

3. Plaintiff AstraZeneca Pharmaceuticals LP is a limited partnership organized and existing under the laws of the State of Delaware, with its principal place of business at 1800 Concord Pike, Wilmington, Delaware 19803.

4. Mylan Pharmaceuticals Inc. ("Mylan") is a company organized and existing under the laws of the State of West Virginia, with a place of business at 781 Chestnut Ridge Road, Morgantown, West Virginia 26505.

5. Defendant Kindeva Drug Delivery L.P. ("Kindeva") is a company organized under and existing under the laws of the State of Delaware, with a place of business at 42 Water Street, Building 75, St. Paul, Minnesota 55170.

II. SYMBICORT

6. Plaintiff AstraZeneca Pharmaceuticals LP is the holder of New Drug Application ("NDA") No. 021929 for Symbicort®, which was approved by FDA on July 21, 2006.

7. Plaintiff AstraZeneca Pharmaceuticals LP sells and distributes Symbicort® throughout the United States.

8. The '247 patent was submitted to FDA by AstraZeneca to be listed in FDA's Approved Drug Products with Therapeutic Equivalence Evaluations (the "Orange Book") for Symbicort®.

9. The active ingredients of Symbicort® are budesonide and formoterol fumarate dihydrate.

10. Symbicort® also contains the inactive ingredients polyvinylpyrrolidone (PVP with a nominal K-value of 25) ("PVP K25") and polyethylene glycol with an average molecular weight of 1000 ("PEG 1000") and the propellant l,1,1,2,3,3,3-heptafluoropropane ("HFA 227").

11. Symbicort® is a prescription drug approved for the treatment of asthma in patients 6 years of age and older and maintenance treatment in patients with chronic obstructive pulmonary disease including bronchitis and emphysema.

12. Symbicort® is an embodiment of claims 1–3 and 5–6 of the ’247 patent.

III. THE ’247 PATENT

13. The ’247 patent is entitled “Composition for Inhalation” and was issued by the United States Patent and Trademark Office (“PTO”) on January 1, 2019.

14. The ’247 patent issued from U.S. Application No. 15/427,425 (“the ’425 application”), filed with the PTO on February 8, 2017.

15. The ’247 patent claims priority to Swedish patent application 0200312 (the “312 application”), filed on February 1, 2002.

16. Nayna Govind and Maria Marlow are the named inventors of the ’247 patent.

17. JTX-2006 and JTX-2022 are true and accurate copies of the ’247 patent.

IV. ANDA NO. 211699 AND THE ANDA PRODUCTS

18. 3M, through its 3M Drug Delivery Systems division, submitted ANDA No. 211699 (“the ANDA”) to FDA under 21 U.S.C. § 355(j), in order to obtain approval to engage in the commercial manufacture, use or sale in the United States of Budesonide and Formoterol Fumarate Dihydrate Inhalation Aerosol, 80 mcg/4.5 mcg and 160 mcg/4.5 mcg (“the ANDA Products”), prior to the expiration of the ’247 patent.

19. The ANDA Products are generic versions of the two dosage forms of Symbicort®, the Reference Listed Drug (“RLD”).

20. By letter dated October 11, 2019 (“Notice Letter”), Mylan notified Plaintiffs that it had submitted a Paragraph IV certification under 21 U.S.C. § 355(j)(2)(A)(vii)(IV) as to the

'247 patent to obtain approval to engage in the commercial manufacture, use, or sale of the ANDA Products prior to the expiration of the '247 patent.

21. Kindeva will manufacture the ANDA Products.

22. The ANDA Products contain the active ingredients budesonide and formoterol fumarate dihydrate.

Dated: May 11, 2022

Respectfully submitted,

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